

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

REC'D 31 MAR 2005

Y/EPD PCT

Applicant's or agent's file reference 2002002-WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00922	International filing date (day/month/year) 19.12.2003	Priority date (day/month/year) 20.12.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/00		
Applicant COLOPLAST AS et al.		



- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 23.06.2004	Date of completion of this report 30.03.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Rosenblatt, T Telephone No. +49 89 2399-8732 

**INTERNATIONAL PRELIMINARY
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International application No. **PCT/DK 03/00922**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-17 as originally filed

Claims, Numbers

1-19 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	6,9-12,14,16-19
	No: Claims	1-5,7,8,13,15
Inventive step (IS)	Yes: Claims	6,9-12,14,16-19
	No: Claims	1-5,7,8,13,15
Industrial applicability (IA)	Yes: Claims	1-19
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1 = US-A-5 887 593,
D2 = WO-A-02/36192.

2. The subject-matter of claim 1 lacks novelty (Art. 33(2) PCT) in view of the device for opening the human bladder known from document D1, see fig. 2, 3 and 4, which disclose

- an oblong member (12) for opening the urethral sphincter, said oblong member comprising means for draining fluid from the bladder (17,26),
- a guide member for (20) manipulating the oblong member, wherein the guide member in a first configuration is bend and the guide member allows unfolding from said first configuration into a second configuration allowing for insertion of the oblong member in a unitary tract (cf. col 6, lines 24-41).

Although feature 20 in D1 is called a reservoir tube, it is submitted that this means also serve to the insertion of the device in the urethra, and may also be called a guide member, since it guides at least the introducer tool 50.

Since all features of claim 1 are anticipated by the device of D1, the claim does not meet the requirement of Art. 33(2) PCT.

- 2.2 The subject-matter of claim 1 is considered to lack novelty also in view of the devices known from D2, the claimed oblong member being identified with the elongated body 10, and the claimed guide member being identified with the guide thread 19. The thread is initially bent (rolled) in its first configuration and allows for unfolding into a second configuration so that the oblong member may be inserted in a urinary tract.

3. Dependent claims 2 to 5, 7, 8, 13, 15, do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

- 3.1 The additional features of the following claims are all known for example from the device of D1, so that these claims do not meet the requirement of novelty (Art. 33(2) PCT):
- claims 2, 3, 4 : see figures 2 and 3;
 - claims 5, 7 : see col. 6, lines 8-10;
 - claim 8 : implicit, since the means 20 may be gripped for example during insertion;
 - claim 13 : cf. col. 5, lines 4/5;
 - claim 15 : implicit, since the claim only states that the oblong member may be bend, which is certainly true also for the oblong member 12 of D1, since it is composed of flexible materials (cf. col. 4, line 3 to col. 5, line 10).
4. The combination of the features of dependent claim 6 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows: The "guide member 20" of D1 adopts said first bent configuration in its natural state and has to be straightened manually by the user during the introduction of the tool 50. Hence it is not adapted to unfold during un-packing from a package, so that the requirement of novelty (Art. 33(2) PCT) is met. This distinguishing feature provides for the effect of space-saving storage and linked to this carrying the device in discrete manner by the user while permitting easy manipulation. There is also no indication in the available prior art to modify the device of D1 in this sense, so that the requirement of inventive activity appears to be met (Art. 33(3) PCT).
- 5.1 The combination of the features of dependent claim 9 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows: A slack tube being less rigid than the oblong member, as defined in claim 9, enabling urine to be drained to a place of disposal (e.g. collection bag), which allows for better urine flow control. Also this feature is not known from D1, so that the requirement of novelty is met. Also it is not rendered obvious by the available prior art, so that the subject-matter of claim 9 also appears to be inventive.
- 5.2 Claims 10 to 12 depend on claim 9 and claims 13 to 19 make reference ("according to any of the preceding claims") to it and hence may be considered to also meet the requirements of novelty and inventive activity if regarded as dependent on claim 9.

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6. The device according to claims 1 to 19 may be industrially manufactured and commercialised and hence meets the requirements of industrial applicability (Art 33(4) PCT).
7. It is noted that the following requirements of the PCT are not met by the present application:
 - two-part form of independent claim, Rule 6.3(b) PCT,
 - reference signs in the claims, Rule 6.2(b) PCT,
 - acknowledgement of prior art (D1), Rule 5.1(a)(ii) PCT.